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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,005	04/20/2001	Edward G. Kirby	RUT.98-0046	1373
110	7590	12/22/2003	EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN			KALLIS, RUSSELL	
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PHILADELPHIA, PA 19103-2307			1638	

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

S.17

Office Action Summary

Application No.	Applicant(s)	
09/763,005	KIRBY ET AL.	
Examiner	Art Unit	
Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 September 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,7-12,16,18,20-22 and 29 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,7-12,16,18,20-22 and 29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3-6, 13-15, 17, 19, 23-28, 30, 31-40 have been cancelled. Claims 1, 2, 7-12, 16, 18, 20-22, and 29 are pending and examined.

The rejection of Claims 17 and 30 under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's amendments.

The rejection of Claims 1 and 7 under 35 U.S.C. 102(e) as being anticipated by Coruzzi *et al.* is withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 112

Claims 1 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn a plant expression cassette comprising a nucleic acid that encodes a glutamine synthetase from gymnosperm; a gymnosperm nucleic acid sequence that has at least 70% sequence identity to SEQ ID NO: 3 and [glutamate] glutamine synthetase activity; or a gymnosperm nucleic acid sequence that hybridizes to SEQ ID NO: 3 under conditions of moderate sequence identity.

Applicant describes a single glutamine synthetase coding sequence from a gymnosperm that was known in the art (Canton *et al.* *Plant Mol. Biol.*, 1993, Vol. 22, No. 5, pages 819-828) of SEQ ID NO: 3.

Applicant does not describe the composition or structure of other gymnosperm glutamine synthetase encoding cDNAs or any nucleic acids having at least 70% sequence identity to SEQ ID NO: 3; or any sequence s that hybridize to SEQ ID NO: 3 under hybridization conditions of moderate stringency having [glutamate] glutamine synthetase activity.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a plant expression cassette comprising SEQ ID NO: 3 encoding a protein having glutamine synthetase activity, does not reasonably provide enablement for a plant expression cassette comprising a nucleic acid sequence that has at least 70% sequence identity to

SEQ ID NO: 3 encoding a protein having glutamine synthetase activity or a nucleic acid sequence that hybridizes to SEQ ID NO: 3 under the hybridization and wash conditions of low stringency recited in Claim 7 part (b) encoding a protein having glutamine synthetase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant broadly claims a plant expression cassette comprising an isolated nucleic acid sequence encoding a glutamine synthetase from gymnosperm.

Applicant teaches an isolated nucleic acid of SEQ ID NO: 3 encoding a glutamine synthetase from gymnosperm.

Applicant does not teach a plant expression cassette comprising a nucleic acid sequence that has at least 70% sequence identity to SEQ ID NO: 3 encoding a protein having glutamine synthetase activity, other than SEQ ID NO: 3; or a nucleic acid sequence that hybridizes to SEQ ID NO: 3 under the hybridization and wash conditions of low stringency encoding a protein having glutamine synthetase activity recited in Claim 7 part (b).

The unpredictability in isolating nucleic acid sequences under the low stringency and wash conditions recited in the claims would be greater than the unpredictability described by Fourgoux-Nicol *et al.* while isolating DNA fragments using stringent hybridization conditions, wherein the stringent conditions did not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al (1999, Plant Molecular Biology 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65⁰C (page 859, left column, 2nd paragraph).

Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2). Further, Applicant has not taught the conserved regions and essential catalytic residues of SEQ ID NO: 3 so that one of skill in the art could make a nucleic acid sequence having at least 70% sequence identity to SEQ ID NO: 3 and also having glutamine synthetase activity, thereby increasing nitrogen metabolism when expressed in a plant.

See *In re Fisher*, 166 USPQ 18, 24(CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

Given the unpredictability in the art as to which substitutions to SEQ ID NO: 3 that would comprise a nucleic acid having at least 70% sequence identity to SEQ ID NO: 3 would be tolerated and still encode a glutamine synthetase or which polynucleotides would hybridize to SEQ ID NO: 3 under conditions of low stringency and encode a protein having glutamine

Art Unit: 1638

synthetase activity; the breadth of the claims encompassing a plant expression cassette comprising a nucleic acid encoding a glutamine synthetase from gymnosperm; the lack of guidance in the examples of the specification or in the prior art as to which substitutions to SEQ ID NO: 3 or which polynucleotides that hybridize to SEQ ID NO: 3 would best serve the invention; although one of skill in the art can readily make nucleotide substitutions or isolate polynucleotides by Southern hybridization one would not know based upon Applicant's disclosure which embodiments would be inoperable and predictable eliminated, and thus undue trial and error experimentation would be needed by one skilled in the art to make and clone a multitude of non-exemplified variants of SEQ ID NO: 3 and would require one of skill in the art to test the non-exemplified variants of SEQ ID NO: 3 in a myriad of non-exemplified plants for increased nitrogen metabolism to alter the phenotype in a multitude of non-exemplified transformed plant species. Therefore, the invention is not enabled for the scope set forth in the claims.

Claims 7, 11-12, 16, 18, 20-22 and 29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for the reasons of record set forth in the Official actions mailed 7/08/2002 and 4/11/2003. Applicants arguments filed 1/14/2003 and 9/15/2003 have been considered but are not deemed persuasive.

At Claim 7, lines 2, 6, and 16, "glutamate" should be --glutamine-- for proper antecedence.

At Claim 11, "the" should be --a--. Applicant has not responded to this rejection.

Claim 12 recites the limitation "said plant" in line 2. There is insufficient antecedent basis for this limitation in the claim. The claim suggests transforming an already transformed plant. Applicant asserts that there is antecedent basis for said plant (response page 18). Applicant's arguments are considered non-responsive because the previously recited plant is a transformed plant whereas the expression cassette is introduced into an untransformed plant. It is recommended that "said plant" be changed to --a plant--.

At Claim 21, line 1, "A reproductive unit" is indefinite because it is not clear, whether it refers to a seed, a flower or a sexual gametophyte. Applicant asserts that a reproductive unit can refer to any of the above mentioned units. Further, Applicant asserts that the term 'reproductive unit' broadly encompasses any unit that facilitates reproduction (response page 19). Applicant's arguments are not persuasive because 'reproductive unit' is not clearly defined in the art or in the specification. Hence, the metes and bounds of the claims are unclear.

Claim Rejections - 35 USC § 103

Claims 1, 2, and 7-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Coruzzi *et al.* (U.S. Patent 5,955,651 with an effective filing date of June 7, 1995), in view of each of (Canton F. *et al.* Plant Molecular Biology, 1993 Vol. 22, pp. 819-828) and Applicant's admission. This rejection is maintained for the reasons of record set forth in the Official actions mailed 7/08/2002 and 4/11/2003. Applicants arguments filed 1/14/2003 and 9/15/2003 have been considered but are not deemed persuasive.

Applicant asserts that it is well known in the art that GS1 from angiosperms and gymnosperms are biochemically and functionally distinct in their regulation and expression patterns and since the GS1 enzyme of pea, taught by Coruzzi and pinus taught by Canton do not

share these features they are not functional equivalents and hence it is not obvious to substitute one for the other (response pages 16-17). Applicants arguments are directed to limitations that are not in the claims. The claims are drawn to a nucleic acid encoding a glutamine synthetase from gymnosperm or a nucleic acid sequence from a gymnosperm having 70% sequence identity to SEQ ID NO: 3 encoding a protein having glutamine synthetase activity. Applicant's arguments directed to expression profiles of either pea or pinus GS1 with respect to tissue expression and developmental expression are not the limitations recited in the claims and thus, the pea and pinus nucleic acids encoding GS1 enzymes are functional equivalents and it is obvious to substitute one for the other.

Applicant asserts that the Corruzi sequence does not have 70% sequence identity to SEQ ID NO: 3 based on submitted alignments of Exhibits A and B (response page 17). The Examiner submits that Applicant has not specified alignment parameters and as such, submits an alignment showing that M20663 of the GS1 from pea has 82.504% sequence identity to X69822 or SEQ ID NO: 3 see arguments supra.

Applicant asserts that the expression vectors of the instant claims when transferred into angiosperms have an unusual accumulation of pine GS1 in photosynthetic tissue and a higher transformation efficiency than that taught by Corruzi (response page 18). Applicant further asserts that no motivation has been provided by the teachings of Corruzi (response page 18). Applicant is invited to inspect the title and abstract of U.S. Patent 5955651 and column 21 and 29 where motivation is provided to make plants with increased nitrogen metabolism.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an unusual

accumulation of pine GS1 in photosynthetic tissue and a higher transformation efficiency than that taught by Corruzi) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

No claim is allowed.

Claims 12, 16, 18, 20-22, and 29 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest methods of transforming poplar and transformed poplar plants comprising isolated cDNA from *Pinus sylvestris* encoding a glutamine synthetase of SEQ ID NO: 3, wherein said poplar plants have increased growth.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

Russell Kallis Ph.D.
November 25, 2003



AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
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